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Atty. Docket No.: P66606US0

REMARKS

The Office Action mailed March 26, 2004, has been carefully reviewed and, in view of the following remarks, favorable reconsideration of this application is respectfully requested. Claims 22-29 and 40-44 are pending.

The Examiner rejected claims 22-27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,505,074 to Boveja et al. ("Boveja") in view of U.S. Patent No. 3,662,758 to Glover and further in view of U.S. Patent No. 5,188,104 to Wernicke et al. ("Wernicke").

As set forth in independent claim 22, the present invention is directed to a method for controlling an overactive bladder. Accordingly, the method includes the steps of detecting nerve signals from nerves innervating the bladder and, on the basis of such signals, detecting a bladder event. Electrical pulses are then generated in response to the detected bladder event, and such electrical pulses are used to stimulate afferent nerves in order to *inhibit detrusor contraction* of the bladder. This is not shown or suggested by the prior art.

Boveja discloses an implanted apparatus which treats incontinence by continuous stimulation of a sacral nerve. As correctly noted by the Examiner, Boveja does not disclose that the stimulation can be given as a response to a detected or sensed

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signal, whether from nerves innervating the bladder or otherwise. Nor is there any indication of the possibility of such sensing or detecting because Boveja is an open loop system. Being directed to continuous stimulation, no detection of signals is necessary, and therefore a need or use for the detecting of nerve signals cannot be realized from Boveja; such detection capability belongs to another technological field.

Glover describes a stimulator apparatus for "muscular organs" with an external transmitter and an implantable receiver. The system comprises a stimulation part and a sensing part, with the stimulator being intended to generate muscle contraction.

More specifically, the Glover apparatus includes a set of electrodes adapted to apply an electronic signal to a muscular organ and, in the case where the organ of concern is the bladder, the electrodes are placed on the bladder wall to impose contraction of the bladder. It is neither taught nor implied in Glover that individual nerve connections, e.g. "afferent nerves" as claimed in the present application, can be identified and stimulated. Hence, the general bladder wall stimulation taught by Glover is not analogous to the stimulation of pudental nerve afferents as claimed by the present invention.

The mechanism by which the Glover apparatus works is that the applied stimulus causes emptying of the bladder by electronic

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stimulation of the bladder muscle structure which induces a contraction thereof. This is useful in situations where the patient's nerve connections are impaired in such a way that the muscle structure cannot be activated for contraction through nerve stimulation, even if the bladder is full. The present invention, by contrast, is directed toward the opposite result in that an electric stimulus is applied to single nerve connections and is so applied in order to *inhibit* nerve signals that cause contraction of the bladder, thus *avoiding* contraction and the emptying of the bladder.

Furthermore, while the Glover apparatus includes means to detect the volume of urine of the bladder, the sensing part of the apparatus consists of a pair of electrodes placed on the bladder wall and the sensing is done by applying an electrical stimulus across the bladder between the electrodes to detect the impedance of the material (urine) between the electrodes. The magnitude of the measured impedance is an indicator of the volume of material disposed between the electrodes, and thus is an indicator of the fullness of the bladder.

The bladder being "full" however, is a passive situation or state. It is in no way a *bladder event*. The bladder itself does not "decide" when it is full, and "full" is a relative term. Ultimately, the bladder will only be full at the point (volume)

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where it will burst. However, the "decision" that the bladder is full is made by a preprogrammed control function of the disclosed apparatus well before this ultimate state of fullness arises (hopefully). The point or volume at which the bladder is considered "full" can thus be arbitrarily set, and therefore is not indicative of an event but rather of a passive state. In any case, to the extent that what is detected can be called an event, it should rather be called "an apparatus event" and not a "bladder event". And since the bladder volume does not change upon initiation of a bladder contraction, Glover's volume sensing method clearly cannot be used to detect the onset of a bladder contraction.

The term "bladder event" is further elaborated or specified in the present application and in the main claim (claim 22) in that the phrase "detecting a bladder event from the nerve signals" indicates that a bladder event is defined as an action involving nerve activity. Therefore, the action in Glover of electrifying the bladder to obtain information as to its passive state, i.e., fullness, is in no way indicative of the method of the present invention in which information of an action, i.e., a bladder contraction constituting a bladder event, is passively measured by detecting a nerve signal. Instead, these methods are completely opposite.

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Finally, the sensing part of the Glover apparatus does not provide automatic closed loop control but, when the bladder is determined to be full, Glover stimulates the bladder wall to empty the bladder. The object of the present invention, on the other hand, is not to obtain a bladder contraction (and thereby bladder emptying). On the contrary, the purpose of the present invention is to *inhibit* an emerging bladder contraction to prevent leakage of urine.

Wernicke describes a method and apparatus for treating eating disorders by nerve stimulation. Stimulation is conducted through electrodes on the vagal nerve and can be based on the fullness of the stomach, which is monitored either by estimating stomach volume (impedance) or by counting the number of swallows (by impedance changes of the esophagus). In this case, "events", namely acts of "swallowing", are detected on the basis of the changing impedance of the material passing by the sensors.

However, Applicants cannot see how this teaching in Wernicke can be applied in the context of detecting a bladder event. Certainly no description of this is indicated in the Wernicke patent. Further, it is not possible to conclude from Wernicke that detecting a nerve signal in order to determine the onset of a bladder event is desirable or even possible.

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Taken together, Wernicke's method is analogous to Glover's method of monitoring bladder volume, and none of the cited prior art documents show that a nerve signal can be used to detect a bladder event.

In summary, none of the cited references relate to a method for controlling an overactive bladder, and none disclose the detection of signals from nerves innervating the bladder in order to detect a *bladder* event. In none of the cited references is there any disclosure of the generation of an electrical pulse as a response to a detected bladder event, nor is there anything to suggest that a stimulus be delivered to afferent nerves to the bladder. The continuous stimulation of Boveja and the delivery of stimulus to muscles in the vicinity of the bladder as in Glover is simply not analogous to the method being claimed by the present invention. Furthermore there is nothing in the prior art to suggest the stimulation of afferent nerves in order to *inhibit detrusor contraction*. Hence, even if the three patents were somehow combined, although Applicants can see nothing within these documents to provide an incentive to do so, the present invention would not result therefrom.

The bladder is a distinct anatomical region with a distinct physiology, the features of which are relied upon by the present invention. Bojeva and Glover, to the extent they concern

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the bladder, do not contain any indications whatsoever pointing in the direction as to how to solve the problem to which the present application is directed. Further, it is questionable whether apparatuses or methods concerned with other organs can indicate how to treat malfunctions of the bladder.

For at least the foregoing reasons, claim 22 is patentable over the prior art. Claims 23-29 and 40-44 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein. Reconsideration and allowance of the pending claims is therefore requested.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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